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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,746	07/22/2003	Alastair McIndoe Hodges	104978-0006	6474

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EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	
ART UNIT	**PAPER NUMBER**
1753	

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/624,746	HODGES ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/981,385.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Rejections pending since the Office action of June 28, 2005

1. The provisional double patenting rejections based on U.S. application No. 10/624,795 are maintained.

2. The provisional double patenting rejections based on U.S. application No. 10/624,823 are maintained.

3. The provisional double patenting rejections based on U.S. Patent No. 6,284,125 B1 are withdrawn.

4. All of the rejections under 35 U.S.C. 103(a) are withdrawn.

Response to Arguments

5. Applicant's arguments filed December 30, 2005 have been fully considered but they are not persuasive. Applicants argue that the spacing between the electrodes in Diebold is not only due to the spacer (43), but also due to a second insulating layer (5) over the working electrode and a second insulating layer (34) over the counter electrode. The examiner acknowledges this observation and has addressed it in the new rejections below. It will noted here that the contribution to the spacing between the electrodes in Diebold by the second insulating layers is minimal compared to that of the spacer.

Applicants argue that decreasing the thickness between the electrodes in Diebold is more than scaling down the thickness of the intermediate layers because Cottrell analysis would be adversely affected. First, Applicants have not indicated a lower limit, such as 200 microns, below which Cottrell analysis is so inaccurate that the sensor will be rendered effectively inoperable. So, a scaled down Diebold sensor may only be slightly inaccurate, but still be able to make measurements and meet Applicants' *structural* limitations of the *device* claim. Second, the suggested measurement method by Diebold corrects for deviations from a predetermined Cottrell relationship. See in Diebold col. 13:9-26, especially lines 23-26, which cite U.S. Pat. No. 5,243,516 ("White"), and in White the abstract and col. 2:35-59. So, deviations from expected Cottrell relationship due to small spacing between the electrodes could also be corrected using the measurement method of Diebold by programming in correction

factors. Last, a distance between working and counter electrodes of only 100 microns is needed for a measurement signal that has an expected Cottrell current at current flows of 0-50 microamps. See Pottgen et al. (US 6,153,069) col. 7:44-58. This distance is well within Applicants' claimed range. Furthermore, since the current in Diebold is on the order of nanoamps (Figure 9), even a smaller distance than 100 microns between the electrodes would be expected to follow a Cottrell relationship: 'Practical considerations, however, dictate that the spacing d be as small as technically feasible to minimize substrate, reagent, and sample requirements" (Pottgen col. 7:66 – col. 8:10).

Applicants argue that Strauss "fails to provide any motivation for spacing electrodes according to Applicant's invention." Strauss was only cited to show the technical feasibility and commercial availability of very thin Mylar sheets. Diebold provides the motivation of desirability of smaller sample size.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diebold et al. (US 5,437,999) in view of Straus et al. (US 5,089,320) ("Straus"), Kanezawa et al. (US 5,095,407) ("Kanezawa") and "Enthone – Imaging Technologies Update" June 2001/Number 3) ("Enthone").

Addressing claim 1, Diebold discloses a hollow electrochemical cell (Figures 5 and 6) for measuring a concentration of glucose in a blood sample, the h9llow cell comprising

(a) at least one working electrode (11);

(b) at least one counter or counter/reference electrode (48), wherein the working electrode and the counter or counter/ reference electrode are not coplanar (Figure 5) and a separated by a very small distance (implied by Figure 5 and related passages, which disclose thin layers);

(c) a spacer (43) interposed between the working electrode and the counter electrode or counter/reference electrode (Figure 5), where the spacer comprises a non-conductive polymeric material (col. 7:14-18 and col. 7:55-57), and wherein the hollow electrochemical cell has a small effective volume (implied by col. 8:45-50, which discloses that the cell is part of a capillary space); and

(d) a fluid permeable side-wall on a t least one side of eh hollow cell permitting entry of the sample into the hollow cell (right end of capillary 49 in Figure 5);

Diebold does not mention (1) whether the working electrode in the embodiment of Figure 5 is non-metal, (2) having the working electrode and the counter or counter/reference electrode spaced from about 20 microns to about 200 microns, and (3) having the effective cell volume be less than 1.5 microliters

As for having the working electrode be non-metal, Diebold does broadly disclose providing a non-metal working electrode. Diebold states, "A working, counter, or reface electrode element may be produced in accordance with the present invention as shown in Fig. 1. Electrically conducting material **1** (e.g., a noble metal or carbon) is vacuum sputtered or evaporatively deposited onto thin support material **2** ..." [emphasis added].

See col. 3:50-54. The decision as to whether to use a metal working electrode or a non-metal working electrode was within the skill of one with ordinary skill in the art at the time of the invention. The major factors that would be considered are manufacturing cost for and retail price of the electrochemical cell (noble metals, such as gold and platinum are more expensive than carbon) and desired measurement accuracy (electrical conducitivity of the conductive material for the electrode).

As for the working electrode and the counter or counter/reference electrode spaced from about 20 microns to about 200 microns, Diebold discloses using a MYLAR™ film as a spacer (col. 7:14-18 and col. 7:55-57), but does not disclose the thickness. Diebold also discloses using MYLAR™ film of approximately 10 mil (254 microns) thickness as an electrode support (col. 5: 62-67), which if not the same MYLAR™ film as used for the spacer is certainly an obvious variant. As shown by Straus, at the time of the invention MYLAR™ film of only 12.2 microns in thickness was commercially available. See col. 4:53-56. The spacing between the working electrode and counter electrode also has a contribution from a second insulating layer (5) over the working electrode and a second insulating layer (34) over the counter electrode. Diebold that these second insulating layers are a solder resists, such as ENPLATE®DSR-3242 (a negative resist). See col. 4:35-48. Product literature from Enthone discloses that ENPLATE®DSR-3242 could be made less than 1.1 mils thick (27.94 microns), for example 0.5 mils (12.7 microns). See Enthone. Also, it was known at the time of the invention to make a negative type photosensitive epoxy-solder resist (ENPLATE®DSR-3242 is such a resist) only 5 microns thick in a printed circuit board,

which is clearly related art to Diebold. See in Kanezawa col. 8:9-16. Thus, barring evidence to the contrary, such as unexpected results Applicants' claimed distance between the working electrode and the counter or counter/reference electrode of from about 20 microns to about 200 microns is just a matter of scaling the spacer of Diebold, such as by using the 12.2 micron thick Dupont Mylar film disclosed by Straus and thin second insulating layers as disclosed by Enthone and Kanezawa. A smaller spacer will create a smaller electrochemical cell effective volume, which is consistent with the purpose of Diebold: "A method for fabricating high-resolution, biocompatible electrodes is disclosed, allowing production of an electrochemical sensor which is capable of precise analyte concentration determination on a very small sample size. [emphasis added]."

As for the hollow electrochemical cell having an effective cell volume of less than 1.5 microliters, this is just a matter of scaling the spacer of Diebold. Diebold is directed to a small volume sensor and discloses a cell volume of 3 microns. See the abstract and col. 12:35-42. The spacer, by its thickness and the width of the capillary channel, defines the cell volume in Diebold. See Figure 5. It may be made of a plastic film, such as MYLAR™ film. See Figure 5 and col. 7:14-18 and col. 7:55-57. As noted above, at the time of the invention MYLAR™ film of only 12.2 microns in thickness was commercially available. Diebold also discloses using a laser to from a cutout that defines the capillary channel. See col. 7:14-21. Thus, barring evidence to the contrary, such as unexpected results, having an effective cell volume of less than 1.5 microliters is just a matter of scaling the cell volume in Diebold by using a thin enough spacer, such

as using the 12.2 micron thick Dupont Mylar film disclosed by Straus, and/or creating a narrow enough capillary channel by using thin enough laser beam.

Addressing claim 2, as discussed in the rejection of claim 1 Diebold discloses a carbon working electrode.

Addressing claims 3 and 4, Diebold states, "A working, counter, or reface electrode element may be produced in accordance with the present invention as shown in Fig. 1. Electrically conducting material **1** (e.g., a noble metal or carbon) is vacuum sputtered or evaporatively deposited onto thin support material **2** ..." [emphasis added]. See col. 3:50-54. So, barring evidence to the contrary, such as unexpected results, whether to use a noble metal for the counter electrode and a nonmetal for the working electrode is just a matter of optimizing the electrochemical cell (sensor), while minimizing cost.

Addressing claim 6, as stated in the rejection claim 1 above, "The spacer [of Diebold, which is to be used in the invention of claim 1 of copending Application No. 10/624,746] forms a hollow cell and a fluid permeable side-wall on at least one side of the hollow cell permitting entry of the sample into the hollow cell."

10. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Diebold et al. (US 5,437,999) in view of Straus et al. (US 5,089,320) ("Straus") Kanezawa et al. (US 5,095,407) ("Kanezawa") and "Enthone – Imaging Technologies Update" June 2001/Number 3) ("Enthone") as applied to claims 1-4 and 6 above, and further in view of Carter et al. (US 5,126,034) ("Carter") and Bohs (US 5,399,256).

As for the metal being silver, since Diebold discloses that the metal may be a noble metal this is just optimization. In fact, Diebold discloses a counter electrode comprising silver (col. 12:43-55). Ag/AgCl was a common counter/reference electrode composition at the time of the invention. As shown by Carter and Bohs the combination of a non-metal (carbon) working electrode and a silver counter/ reference electrode is not novel. See Figure 1 and col. 2:28-48 in Carter and Figure 5; col. 2:62- col. 3:5;and col. 7:50-53 in Bohs.

As for chloride ions in the blood sample, the type of sample is intended use that does not appear to further structurally limit the electrochemical cell. In a any event, Diebold discloses directly measuring blood (col. 12: 35-42) and blood contains various chloride salts, such as NaCl or KCl.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alex Noguerola
Primary Examiner
AU 1753
March 13, 2006